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MEDICAL DROP BOX (MDB);
A NATIONAL HEALTH INFORMATION EXCHANGE AND MANAGEMENT SYSTEM FOR MEDICAL INDUSTRY

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ABSTRACT… Introduction: National Health Information Exchange (NHIX) Systems are rapidly evolving. Due to the cyber infrastructure and improvements in communication technology, it is possible to share healthcare related data within a geographic region electronically among healthcare related autonomous entities such as physicians, hospitals, test laboratories, insurers, emerging Health Information Organizations (HIO), and even government departments. **Study Design:** Whether data are collected with the RCT, Quasi-experimentation or Triangulation etc., we present to explore a NHIX system for EHR that has also been implemented as a test case. We particularly propose to demonstrate a concept application, Medical Drop Box (MDB) with the key technological components of a future NHIX System for medical industry. **Setting:** Data from different medical settings have been used for testing the new system but the technological development has been done at IIU, Islamabad. **Period:** The proposed system is not time bond in terms of data collection. Basically the proposed system can handle data collected in any chunk of time in the history and can provide information as and when needed in future. **Material & Methods:** With MDB, a person is able to collect his/her health data and share it with the whole medical industry according to his/her own preferences and setting. Besides the technology for handing numerous forms of health care data, the main challenge of NHIX system is to allow individuals and associated medical entities to manage and share their medical information based on personal control and preferences given to each by medical laws, information rights and privacy rules. The main focus in this research paper is to make a standard medical application for the medical data that is in exchangeable format according to the standards defined in HL7. **Results:** The new system is able to make standardized Clinical document for medical data in exchangeable format according to HL7 standard. The MDB is the first step to setup NHIX system. With the help of MDB "Statistical Analyzer" now the health industry of the country can perform a variety of analysis for the future improvements in different health settings. **Conclusions:** The availability of medical data of patients on MDB cloud has improved Clinical Impact, created new Business & Services opportunities and reduced the overall Treatment Cost.

Keywords: Medical Drop Box (MDB), Randomized Controlled Trial (RCT), Health Information Organization (HIO), Health Law 7 (HL7), Clinical Impact, National Health Information Exchange (NHIX).

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INTRODUCTION

In this modern era of information and technology, the healthcare systems are extremely important for the well-being of any country, especially for developing countries like Pakistan.[1] The majority of the healthcare industry in developing countries is working at very poor level.[2] There is nearly non-existent use of Health Information Systems (HIS) even at individual hospital level.[3,4] So, that's why there is a need to improve the current healthcare system with latest technology.

Organized information can radically improve healthcare, just as much as the discovery of a new drug or the invention of a new operational procedure. Let us trace the human life cycle, if collected properly, the size of medical and healthcare data, related to even one individual, can be humongous, often reaching gigabytes and provide extraordinary insight in planning

the correct treatment. One's medical information begins even before a person is born. In developed countries, when a baby is born, its information is stored in the Hospital's Information System (HoIS). The volume of information grows as the baby grows into a full personhood and keeps on growing until their death. The individual faces various illnesses, hospital visits, doctors, undergoes different treatments, takes various laboratory tests, undergoes procedures, takes medicines for cure, etc. all of which generate a wealth of information. An individual's health data remains useful even after their death for his/her close relatives. A number of hospitals in advanced countries are already archiving the patient's information to their HoIS. Since there are billions of patients in this world and similarly thousands of healthcare providers, the task to archiving, integration and meaningful use and analysis of this data is difficult. Figure 1 shows the whole cycle.

Figure 1. Human life cycle with medical treatments overview

A healthcare system involves numerous types of entities ranging from patient, physicians, hospitals, insurers, employers, regulators, researchers etc. Thus, at its heart of it lies the framework (standards, protocols and information architecture) for information exchange. A full-fledged framework addresses many issues such as ease of exchange, privacy of individual, timeliness of treatment, data access and delivery, availability, portability and security issues. In this research our particular focus is on an experimental framework focusing on exchange of individual identifiable information, which is the most critical type of information for improving the quality of treatment from an individual's point of view.

Healthcare information is also one of the most sensitive types of information to exchange where sensitivity arises from the rights, risks, and responsibilities associated with it.[5] The USA and the Western world use healthcare frameworks to ensure that information is available with the privacy and information rights of individuals. In the USA, the Health Insurance Portability and Accountability Acts (HIPAA) provides comprehensive guidance to protect and restrict the health industry to use such information according to their defined space.[6,7] In US, Health Information Technology (HIT) for the exchange of medical data is also under development.[8,9,10] Health department takes an initiative to setup National Health Information Network (NHIN) for the exchange of medical data electronically among different organizations within a region, community or hospital system.[10,11,12] The US HITECH provide funds to establish national health IT setup, where patient's data is to be fired across a national health information highway.[13,14,6] The computerization of records at all levels in hospitals, clinics and other medical institutes will be the progress in Electronic Medical Records (EMR) to create medical Information system.[15]

As there are different formats and varieties in medical data, HL7 has taken the responsibility to provide a concept standardization in medical documents with different formats.[16] HL7 version 2 started with the aim of defining schemes for interchange of records, insurance claims, clinical documents, prescription medication and decision support inside a hospital.[17] HL7 Version 3.0 now aims at all aspects of healthcare data exchange.[18,19] Continuity of Care Record (CCR) standards is used to create electronic summary of patient health.[20] Its purpose is to improve the quality of healthcare by reducing medical errors and ensuring that a patient's full information

profile is available to physicians. Continuity of Care Document (CCD) is another similar standard to HL7/Clinical Document Architecture (CDA release 2.0). CCD uses XML-based markup standard intended to specify the encoding, structure, and semantics of clinical documents for machine exchange.[5,21] Therefore, the patient's summary information can also be shared by all computer applications, including web browsers and EHR software systems.

The demand for medical data exchange among different countries is increasing at an alarming rate. As large number of people travel abroad, they sometimes need to visit hospitals. In such case, doctors may need to access history of the patient for proper treatment. To facilitate this process, clinical data must be exchanged internationally.[13,22]

In Pakistan, like many other developing countries, there is a great awareness to modernize the healthcare system, though there is no concrete plan yet like in the US. Hardly any of the major healthcare facilities in Pakistan, particularly in government sectors, have some HIS in place. In the absence of any required standards and rules framework, there are only a few sporadic efforts to develop a local HIS in a few private institutions, but without the portability standards, these systems are not going to be interoperable and will not serve patient's long term interest.

MATERIAL AND METHODS

The development of a comprehensive National Health Information Exchange (NHIX) is paramount. In this research, we propose such a framework for Pakistan that will allow all entities (hospital, insurance, employers, doctors, labs, individual themselves, emergency room, and perhaps future home monitoring systems) to be involved in treating a person during his/her lifetime and to exchange information efficiently without violating the individual's privacy concerns. This will dramatically improve the healthcare rights of every citizen of Pakistan. In the era of globalization, when most of developed countries are building such an infrastructure, it is also important that the citizens of Pakistan are able to connect to the world's medical infrastructure.

Due to the enormity in medical data management, we developed one of the most compelling application called "Medical Drop Box (MDB)". This will involve the key technological components of a future NHIX system. The objective of this research is to develop a small scale experimental system for the exchange of personally identifiable healthcare information between the patient and his/her service providers in the context of a future National Healthcare Information Exchange (NHIX) of Pakistan as shown in fig.2. MDB allows an individual to systematically receive all personal medical data, he/she has rights to (i) receive, irrespective of their type or format, (ii) archive them indestructibly with security, privacy and individual control, and (iii) make it available to other medical service providers through other relevant entities (such as through a close family member in case of severe illness as ensured in patient's rights).

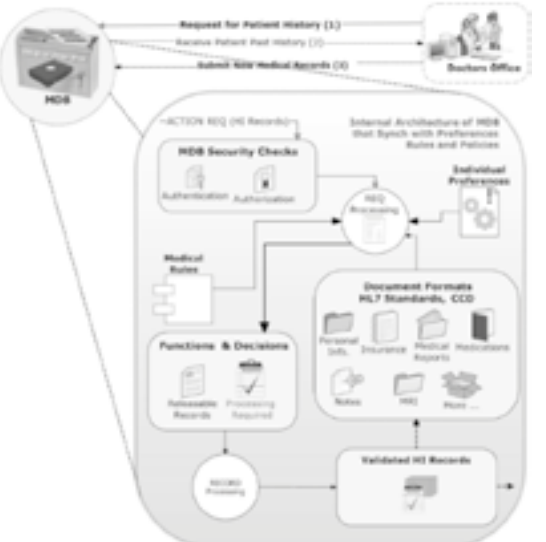


Figure 2. Medical Drop Box Conceptual Design

Each time a patient visits a doctor or any other medical office who wants to access the patient's medical data out of entity scope, the patient provides a small magic key of his/her MDB. The key will be provided to patient using two way authentication procedure. After authentication process, medical data from MDB is accessible

to the doctor/medical office with individual's preferences (steps 1 and 2). The new information is updated into the MDB (step 3) after the treatment. These steps are repeated each time the patient visits any other new facility, the MBD gets richer. Different functions are performed internally in MDB as shown in fig.3. These functions activate automatically as the request will generate from any medical entity to access the MDB. These functions like Security Check, Medical Rules, Individual Preferences, HL7 Standard Documents CCD or CCR Conversion, Lab Reports and Release of Documents, are performed according to the requirement of request.

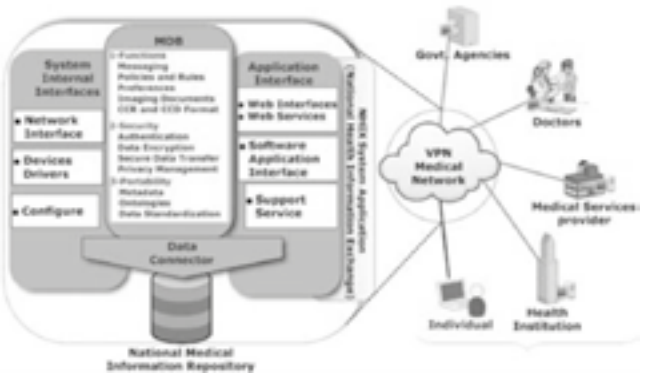


Figure 3. NHIX Application Access with Medical Drop

Individual Preferences in MDB

Individual's preferences are the privacy settings of medical data by individual. For privacy management the individual can set his/her medical preferences about the data whether to share with the others or not in MDB environment. When a request is generated by any medical entity to access or for the release of medical information, those medical preferences are also checked. These preferences for privacy settings are overlooked by law in case of emergency or data required by the law enforcement agencies.

MDB Deployment and Dynamic Architecture

The patient's medical data is updated in National Medical Information Repository through the Regional Health Information Exchange networks (RHIX). The regional networks are connected to the NHIX for the exchange of information within the country as shown in fig 4. The NHIX (Pakistan) will be connected through international peering network with NHIX (World) which will make the MDB information accessible from all over the world.

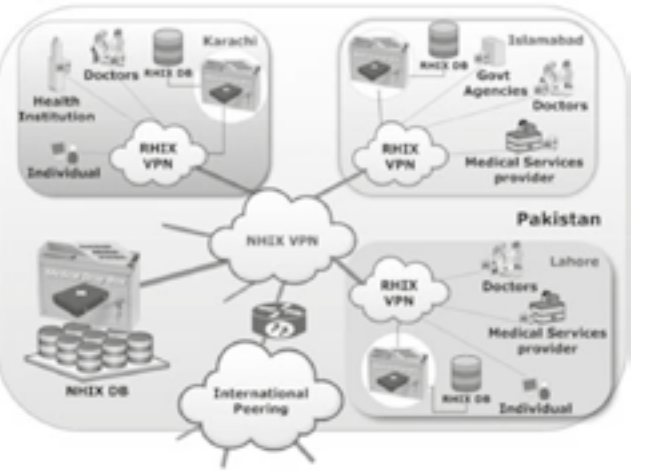


Figure 4. NHIX Deployment with Medical Drop

MDB Security Checks

In this application we assume that all the medical entities are authorized and authenticated. But we will adopt two way authentication procedure for the access of individuals MDB. Medical Information security is the most important part in MDB for data exchange. The information that is exchanged among medical entities should be considered trustworthy and secure. The security refers to three principles.

1. It must be ensured that the information is passed between participating NHIX organizations.
2. The information integrity passed across the NHIX must be ensured for every transaction.
3. Any information that is passed through NHIX can only be read and understood by participating NHIX organizations.

The implementation of above mentioned qualities is possible through the creation of a trustworthy environment. Security of medical data at all levels must be ensured during i.e. access, transmission, and storage. Security gateways are implemented to setup between the local area networks and internet that separate the MDB applications and database from the external networks of specific

country, which stops the visitors from directly accessing the country's server. The servers are fully equipped with proxy, SSL and virtual private network (VPN).

All medical information of patient is managed by MDB. Before an entity or a user executes a function for access or to exchange the information, the access control list and authentication process are executed to verify whether this entity has the permission to perform that operation. So the MDB makes sure that the entity is authenticated and legitimate to perform the particular operations. Similarly when health information is exchanged and transmitted on the network, there is the chance of theft and decryption. Therefore the information is encrypted and transmitted on the SSL VPN. The privacy of individual/patient and authenticity of medical entity is very important.

Clinical Document Generation in MDB

Continuity of Care Record (CCR) is a standard defined by HL7, which is used to create the electronic health summary of patient. It contains information of patient related to health, such as healthcare provider information, allergies, medication lists, demographics, insurance and recent medical procedures. Continuity of Care Document (CCD) is another similar standard which completely satisfies HL7 standard i.e. Clinical Document Architecture (CDA). CCD format is used to create the medical data with MDB. CCD uses the XML-based standard to specify the structure, encoding and semantics of clinical document for the exchange of medical information. Due to XML based structure, patient's information can be used by all computer applications, including web browsers and health software.

Medical Drop Box stores the information in the form of CCD format. MDB also uses BaseX database that stores the information only in XML. In Medical Drop Box XML file for each entity is created at the registration time that contains all the information related to the entity, which also contains the history of medical entity. Similarly the patient's file is updated after each medical checkup so that history is maintained. Patient's preferences and policies related to medical entities are also in the form of XML. The structure of the user/patient profile stored in BaseX database in the form of XML is shown as below.

```
<users>
<user MDB_ID="123" Password="123"/>
<user MDB_ID="15072014abc"
Password="15072014abc">
<personalinfo> <firstname>fname</
  firstname>
<lastname>lname</lastname>
<dob>15-07-2014</dob>
<maritalstatus>Single</maritalstatus>
<mothername>abc</mothername>
<fathername>abcd</ fathername>
<guardianname>abcde</guardianname>
<gender>Female</gender>
</personalinfo> <contactinfo/>
<employinfo/>
<preferences/> <statistics/>
<miscellaneous/> <insuranceinfo/>
<accounts/>
</user>
</users>
<admins>
<admin MDB_ID="admin" Password="admin"/>
</admins>
```

Clinical document is used by MDB to store medical data, which is created to follow the HL7 standard shown in Appendix A. CCD contains all the history of the patient and each visit is added a different XML tag. On each visit, this document file is updated with new time stamp and contains information of disease, doctor, prescription, medication, health service provider tags and the user/patient related CCD file also contains the information related to privacy and individual preferences to access Health Information.

Duration

Duration can better be understood as data collection time and processing time.

Data Collection Time

The proposed system is not time bond in terms of data collection. Basically the proposed system can handle data collected in any chunk of time in history. Currently database of our system has been populated for the purpose of testing and

information generation with dummy data with real parameters that assures its capacity to deal the real data without any time constraints.

Processing Time

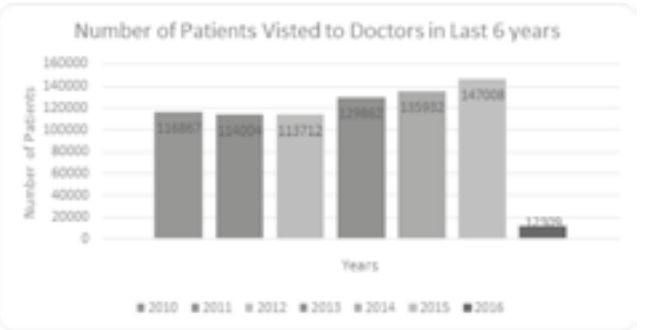
The proposed system has been built using latest development tools to provide the best possible processing speeds. Further improvements regarding hardware and software tools can be made as and when needed depending upon the volume of data and the efficiency required.

RESULTS

The Information stored in MDB is in the form of XML. The data from XML files can be accessible in any web or desktop based medical application. So it can be easily exchanged among different medical networks. As all the medical entities contain their own specific interface, each entity can only access or share data in MDB through its interface. In this prototype we have developed the interface for Doctor, Patient, Labs, Medical Insurance Provider, Hospital and Medical Store. In Appendix B Dashboard and Doctor's interface snapshots are shown. In addition there is a complete appointment and medicine prescription system from doctors and hospital point of view that is implemented internally with MDB, which helps to facilitate patients and manage records. The graphs in fig 5, 6 and 7 are just to show some statistical information from MDB on test data. This statistical information shown in the form of graphs is just on simple data (test data is a database populated with dummy data for experimentation) as an example, more complex statistical information can be generated on live data through MDB.

In fig. 5a the graph shows the total number of doctors registered in last ten years in Pakistan. In fig. 5b the graph shows that number of patients visits to doctors in last five year in Pakistan. We can separate any kind of information related to doctors and patients. For example fig. 6a shows

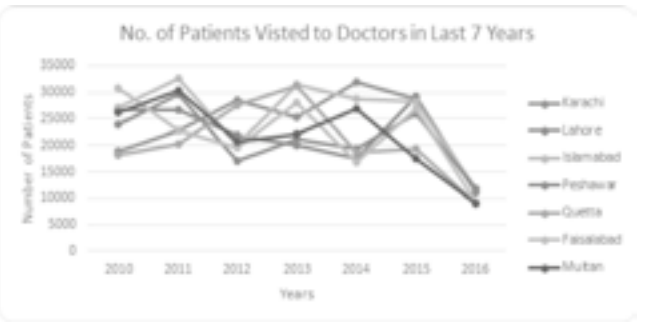
(a) No. of Doctor's Registered in Pakistan Yearly



(b) No. of Patient's Visits to Doctors Yearly

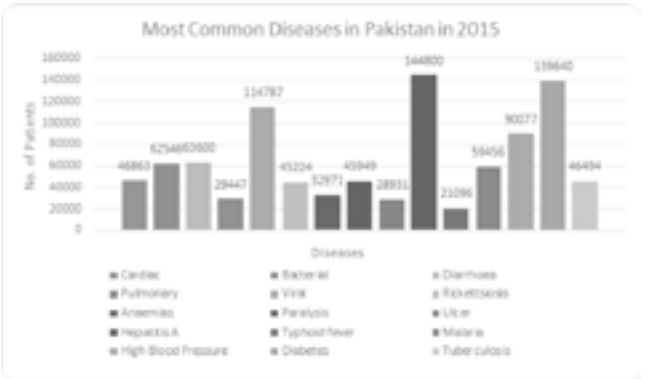
Figure 5. No. of Doctor's Registration and Patient's visits yearly

(a) Doctor's Registration in Different Cities

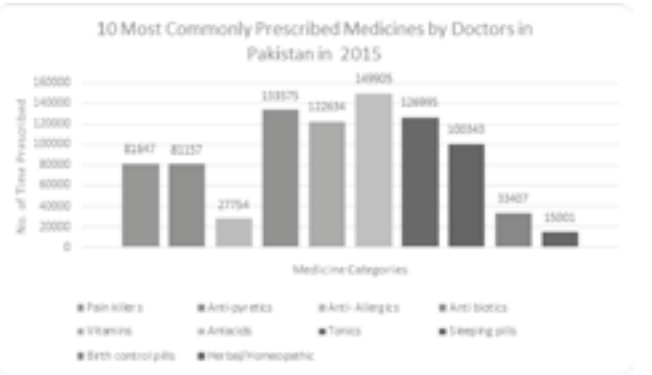


(b) Patient Visit to Doctors in Different Cities

Figure 6. No. of Patient's and Doctor's Registration in Different Cities Yearly



(a) Most Common Diseases



(b) Top Ten Medicine Used

Figure 7. Most Common Diseases and Medicine in Pakistan

the registration of doctors from five big cities of Pakistan.

Similarly fig. 6b shows the number of patients' visits to doctors in different cities. We can extract the information related to patients i.e. how many patients, which kind of diseases in patients, flow of patients in specific hospitals and many more. Similarly we can extract information related to doctors i.e. related to medical specialization, availability of doctors, situation in remote area and many more through MDB from a small city, district, and province up to country level. This will help to make decision on healthcare situations in any part of the world.

Fig 7a shows the most common diseases in Pakistan. We can extract the top diseases in any part of the word from city up to country level. This will help to find out in which area which kind of diseases are more active. We can take decision to control those diseases take precautions for shortage of medicine in that effected area with specific diseases. Similarly fig. 7b shows the most widely used medicine in Pakistan. We can extract which of the medicines has mostly been used in the last five years in Pakistan and which medicine has mostly been used in different cities or in specific area. Pharmaceutical companies have the advantage to analyze this kind of data for the production to control the shortage, the effectiveness of medicine on patients, comparison of similar medicine in market and many more. Any kind of information can be extracted by the medical industry using the MDB and can be analyzed for the future decision.

DISCUSSION

As the health of medical industry in developing country is very poor, the idea behind this study is to develop a prototype application for the medical industry of Pakistan. This application has the ability to make standardized Clinical document for medical data in exchangeable format according to HL7 standard. The MDB will be the first step to setup NHIX system. It is possible to share the Clinical document among different medical entities for their use according to the individual's privacy preferences setting with MDB. Each medical entity then uses data, input data for their purpose and analyze the data to make future decisions.

The most important aspect of MDB is that this clinical document of individual is available in any part of the world. The other aspect of MDB is to be used for the statistical analysis on medical data for future decisions. All types of information can be extracted and evaluated for analysis purpose e.g. related to Doctors, Patients, Medicine, Diseases, Hospitals, Medical Labs, Lab Tests, Health Insurances and Medical Stores etc.
With the help of MDB "Statistical Analyzer" the health industry of the country can perform different analysis related to doctors, medicine, hospitals, patients, birth rate, death rate, requirement of medicines, in any city, district, and province and country level. The most used medicine in

any city to country level that can be used by pharmaceutical companies to analyze this kind of data. Most spreading diseases can be pinpointed in any part of the world so as to be able to take decisions to control the disease in that specific area.

The medical industry can analyze data related to their area and those analysis will help them for future improvement in their facilities. Similarly the other health departments and organizations of the country can analyze all kind of data to implement the government health policies in the country.

CONCLUSION

The medical data of patients are available on MDB cloud in the form of XML. So this XML data can also be used by any other medical application i.e. a web-based or a desktop application. MDB is purely designed and developed for the medical industry to manage data and also exchange this data with other medical entities. Individual's privacy issues are considered according to the individuals preferences. HL7 standards i.e. CCD or CDA formats are adopted in MDB for documents to make its format exchangeable. Medical data is on the cloud and so available all over the world all the time, which will help for the health improvement of not only that individual but also the others facing similar health issues. All kinds of analysis reports for monitoring the health of nation and to make decisions accordingly to resolve the problems.

Clinical Impact: The availability of patient's medical records will create a more precise and accurate treatment. The ability to electronically port medical information, such as imaging results, among different locations will significantly improve patient care especially in developing countries.

Business & New Services: International peering of NHIX's will leverage cross border exchange and trade of medical services. Patients from Pakistan can visit different parts of the world to receive specialized treatment and a Multinational board of specialists may be formed more easily to handle complex cases. Even an ordinary traveler will be able to travel worry free. If they need any emergency medical service from any part of world, critical medical information will be available everywhere. Medical information can travel seamlessly between his/her Pakistani doctors as well as in medical industry.

Cost Impact: The infrastructure is expected to reduce the overall cost of medical services. This will also reduce many redundant diagnostic tests. It will facilitate "paperless" automatic sharing of medical information between patients and doctor's offices. The information will be much better organized and easy to retrieve, and thus will reduce clerical efforts.

Other Impact: NHIX can bring a fundamental qualitative improvement in healthcare with MDB. The national data can be a treasure trove for researchers to make fundamental innovation in finding diseases and effective treatment methods. For Pakistan and developing countries, it will allow medical services to expand into remote regions. It is also believed that the ability to access one's own health information will create a new breed of culturally healthy citizenry.

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"When you can't change the direction of the wind - adjust your sails."

H. Jackson Brown JR.

AUTHORSHIP AND CONTRIBUTION DECLARATION

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